50. (amended) The method of claim [2] 1, wherein said [carbohydrate] nutrient is a lactate.

REMARKS

Claims 1, 2, 17-26, and 28-50 are pending in the application. Claims 26, 28-31, and 36-39 have been withdrawn with traverse as to a non-elected invention. Claim 40 has been cancelled without prejudice or disclaimer. Claims 1, 21, 41, 42, 44, and 46-50 have been amended without prejudice or disclaimer of any subject matter. The amendments are fully supported by the specification. Claims 1, 2, 17-25, 32-35, and 41-50 thus are pending for reexamination.

The United States Patent and Trademark Office has not acknowledged the Revocation and Power of Attorney and Change of Address submitted on March 9, 2000. Copies of the documents and the date- stamped USPTO receipt are enclosed.

Formal matters:

(1) Applicant respectfully requests acknowledgement of the claim for foreign priority under 35 U.S.C. § 119 to DE 19530865.4, filed August 22, 1995, and of receipt by the Patent and Trademark Office of the same.

Support for the Amendments:

The amendments are fully supported by the specification. In particular, support for the amendment of claim 21, is found at least at page 9, lines 27-29. In regard to claims 41 and 44, the use of organic molecular mimics of the insulinotropic peptides which fit the insulinotropic receptor sites is supported at page 9, lines 8-9.

Objection under 37 CFR § 1.75(c):

Claims 49-50 are objected to as in improper dependent form. The dependency of the claims is corrected, and the objection may be withdrawn.

Rejections under 35 USC § 112, first paragraph:

Claims 21 and 47-48 are rejected under 35 USC § 112, first paragraph, for inadequately written description in the specification. Specifically, in claim 21, the examiner alleges that there is inadequate support for "1 pmol/L to 1 nmol/L of blood plasma." Support for this claim limitation is found at least at the bottom of page 9 and at lines 11-13 at page 7. Nevertheless, to expedite prosecution, the range has been amended to express the amount of delivered insulinotropic peptide in terms of moles per kg of body weight of patient per minute.

The examiner further alleges that there is no support for derivatives of the carbohydrates prescribed in claims 47 and 48. The skilled artisan readily would appreciate that useful derivatives of any of these carbohydrates are well known in the art and are embraced by the independent claim. The present claims thus have been amended to expedite prosecution.

Rejections under 35 USC § 102:

I. Claims 1-2, 17-19, 21-25, 32-35, and 40-48 are rejected under 35 USC § 102(b), as anticipated by U.S. Pat. No. 5,118,666 to Habener (" '666 patent"). Applicants traverse the rejection.

The examiner alleges that the single reference teaches every element of every claim at issue. "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), quoting *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988). However, every element of the presently claimed invention is not disclosed in the '666 patent. Specifically, while the '666 patent teaches administration of insulinotropic agents, it nowhere teaches administration of a composition comprising an insulinotropic compound by a parenteral route to a patient in need of parenteral nutrition. For that reason alone, the rejection is improper and now should be withdrawn.

Moreover, the '666 patent nowhere teaches, or even suggests, parenteral administration of a composition that provides an effective amount of nutrients to a patient in need of nutrition. The presently claimed invention prescribes that the nutrients administered

with the insulinotropic agent are in a nutritively effective amount. While the '666 patent teaches a composition containing an insulinotropic agent with excipients that broadly are considered to be nutrients, these excipients are not delivered in concentration effective to sustain the nutritive needs of the patient. For this reason, also, the rejection is improper and should be withdrawn.

II. Claims 1-2, 17-19, 21-25, 32-35, and 40-48 are rejected under 35 USC §§ 102(b) and (e), as anticipated by U.S. Pat. No. 5,614,492 to Habener (" '492 patent"). Applicants traverse the rejection.

The examiner alleges that the '492 patent also discloses each and every feature of the claimed invention. In particular, the '492 patent does not teach, *parenteral* administration of a nutrient and an insulinotropic compound, at the bottom of column 9 through the top of column 10, as alleged by the examiner.

The '492 patent relates to parenteral administration of an insulinotropic compound at column 9. However, the very compounds the examiner alleges are contained in a composition with an insulinotropic compound are described as "contaminants" by Habener (col 9, line 25). At best, Habener teaches and suggests adding lactose with an insulinotropic compound, to increase its stability upon lyophilization, although, even here, Habener indicates that the insulinotropic compound preferably is dissolved only in water (col. 9, lines 43 and 46). The amount of lactose added for this purpose does not provide a nutritively effective amount of lactose, as prescribed by the claims. The '492 patent accordingly neither teaches nor suggests the presently claimed invention, and the rejection should be withdrawn.

Rejection under 35 USC § 103:

Claims 1-2, 17-25, 32-35, and 40-50 are rejected under 35 USC § 103(a), as obvious over "the specification disclosure as to the state of the prior art" in view of the '492 patent "and/or" U.S. Pat. No. 5,424,286 ("Eng").

The examiner alleges that the invention provides the use of insulinotropic compounds in parenteral nutrition compositions "which comprise nutrients for alimentary nutrition." This is a misstatement of the presently claimed invention, which relates to parenteral

administration. It is well known that "parenteral" administration denotes delivery by an non-alimentary route.

Accordingly, Eng does not make up for the deficiencies of the '492 patent. As in the '492 patent, Eng teaches administration of insulinotropic compounds attached to carrier molecules (col. 4, lines 51-56). These molecules are not delivered in nutritively effective amounts – they appear to be delivered as excipients. Further Eng, like the '492 patent, suggests the removal from the insulinotropic compound of the very compounds that the examiner identifies as nutrients (col. 4, lines 57-65). Accordingly, neither reference alone or in combination teaches or suggests the claimed invention, and the rejection now should be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully urged that the present claims are in condition for allowance. An early notice to this effect is earnestly solicited. Should there be any questions regarding this application, the examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

12/1/00
Date

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